K131705
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510(k) Summary

JUL 0 1 2013

SUBMITTER:	Covidien 60 Middletown Avenue North Haven, CT 06473 (203) 492-5299 (T)
CONTACT PERSON:	Katherine Robertson Senior Specialist, Regulatory Affairs
DATE PREPARED:	June 10, 2013
TRADE/PROPRIETRY NAME:	Endo GIA™ Radial Reload with Tri-Staple™ Technology
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staples, Implantable
FDA PANEL NUMBER:	79
PRODUCT CODE:	GDW
CLASS CODE:	Pursuant to 21 CFR 878.4750, an implantable staple is a Class II device.
PREDICATE DEVICE(S):	Endo GIA™ Radial Reload with Tri-Staple™ Technology (K102291); Endo GIA™ Stapler, DST Series™ GIA™ Stapler and DST Series™ TA™ Stapler (K111825)
DEVICE DESCRIPTION:	The single use Endo GIA™ radial reload with Tri-Staple™ technology places three radial (curved) staple rows 60mm in length on each side of a cut line and simultaneously divides the tissue between the third and fourth lines, creating a 60mm curved transection. The medium/thick radial reload places height progressive titanium staple rows. The reloads may be inserted through an access device such as a hand access device or comparable access port. The Endo GIA™ radial reloads with Tri-Staple™ Technology may be used with the Endo GIA™ Ultra Universal, Endo GIA™ Universal, GIA™ Universal and iDrive™ Ultra stapler handles.
INTENDED USE:	The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

TECHNICAL CHARACTERISTICS:

The Endo GIA™ Radial Reload with Tri-Staple™ Technology is substantially equivalent and has not altered the fundamental scientific technology to the predicate devices with regards to stapling technologies.

MATERIALS:

All components of the Endo GIA™ Radial Reload with Tri-Staple™ Technology are identical to the predicate Endo GIA™ Radial Reload with Tri-Staple™ Technology. All materials are similar and are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA:

Design verification and pre-clinical validation studies were conducted to demonstrate that the subject device Endo GIA™ Radial Reload are safe and effective and perform as intended. In vitro and in vivo testing to support the intended use of this device includes:

- In Vitro
  - Firing Force
  - Retraction Force
  - Staple Formation
- In Vivo
  - Free Bleed Evaluation
  - Air Leak Test
  - Burst Evaluation
  - Tissue Grasping and Trauma
- Biocompatibility

The result of these tests demonstrates that the subject device Endo GIA™ Radial Reload with Tri-Staple Technology is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 1, 2013

Covidien
% Ms. Katherine Robertson
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K131705
Trade/Device Name: Endo GIA™ Radial Reload with Tri-Staple™ Technology
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 10, 2013
Received: June 11, 2013

Dear Ms. Robertson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131705

Device Name: Endo GIA™ Radial Reload with Tri-Staple™ Technology

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131705